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Application No.: 10/042,644
Amdt. Dated: September 18, 2006

Reply to Office Action Dated: May 16, 1006

#### REMARKS

Claims 1-52, 69-77, 80-92, and 94-96 are pending in the present application. Claims 80, 81, and 84-91 have been amended and claim 93 has been cancelled without prejudice to or disclaimer of the subject matter contained therein. New claims 94-96 have been added and read upon the elected invention (methods of treating an autoimmune disease in a subject comprising administering an interferon antagonist) as well as the elected species (psoriasis as the autoimmune disease and antibody as the interferon antagonist). The amended and new claims are supported throughout the specification of the application as filed (e.g., at least at page 14, lines 1-26; page 18, lines 3-13; and page 19, lines 1-3).

Claims 1-52, 69-77, and 82-84 have been withdrawn. Because claims 82-84 depend from generic claim 80 that is believed to be allowable, Applicants respectfully request that claims 82-84 to the non-elected species be rejoined, examined, and allowed. See 37 C.F.R. § 1.141.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

## A. Objection to claim 81

Claim 81 was objected to for reciting non-elected inventions. This objection is respectfully traversed.

Claim 81 falls within the elected invention, i.e., Group V—methods of treating an autoimmune disease in a subject comprising administering an interferon antagonist. Claim 81 also reads on the elected species, i.e., species (xv) psoriasis as the autoimmune disease and species (xxvi) antibody as the interferon antagonist.

## B. Claim rejections—35 U.S.C. § 102

Claims 53-68, 78-79, 81-82, and 85-93 were rejected under 35 U.S.C. § 102 as being anticipated by Skurkovich et al. (U.S. Patent No. 5,888,511). The rejection of claims 53-68, 78-79, and 93 is moot, as these claims have been cancelled. The rejection of claims 81-82 and 85-92 is traversed for the reasons that follow.

Claim 80 has been amended to recite a method for treating an autoimmune disease comprising administering to the subject a therapeutically effective amount of a composition consisting essentially of one or more anti-IFN-α antibodies antibodies or antigen-binding fragments thereof. Claim 80 has also been amended to recite that the autoimmune disease is not AIDS.

To anticipate a claim, the reference must teach every element of the claim. MPEP § 2133.

Skurkovich et al. does not anticipate claim 80 (or claims 81-92 and 94-96 depending therefrom) because the reference does not teach treating an autoimmune disease that is not rheumatoid

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arthritis and that is not AIDS as recited in claim 80 with a composition consisting essentially of one or more anti-IFN-α antibodies or antigen-binding fragments thereof.

In the Office Action, the Examiner stated that "[a]lthough Skurkovich et al teach a combination of two or more antagonists/ antibodies to use for the treatment of autoimmune diseases in general. [sic] Skurkovich also teaches that antibodies against a single cytokine can be used (col. 4, lines 1-5)." Office Action dated May 16, 2006, page 4.

However, Skurkovich et al. only discloses the following alleged treatments using antibodies against a single cytokine at the cited portion of the patent:

The administration of monoclonal antibodies to TNF- $\alpha$  has provided encouraging early results in the treatment of patients with severe RA [rheumatoid arthritis].... Also positive preliminary results were achieved in AIDS patients given antibodies or other agents to reduce the level of circulating IFN $\alpha$  in the body ....

Column 4, lines 1-9 (emphasis added). Skurkovich et al. does not disclose effective treatment methods using antibodies (or antigen-binding fragments thereof) against a single cytokine such as IFN-α for the autoimmune diseases recited in claim 80.

In fact, Skurkovich et al. goes on to teach that multiple therapeutic agents are <u>required</u> to effectively treat autoimmune diseases:

However, because autoimmune diseases are complex, often characterized by multiple cytokine abnormalities, <u>effective treatment</u> appears to <u>require the simultaneous</u> <u>administration</u> or <u>utilization of several agents</u>, each targeting a specific cytokine <u>pathway or its by-product</u>. To meet this need, the methods of treatment of the present invention include not only the use of specific antibodies,. [sic] but also provide pleiotrophic autoimmune inhibitors, including antibodies to cytokines and HLA class II antigens, and antigens for the removal of autoantibodies to target cells or DNA.

Column 4, lines 9-19 (emphasis added).

In order to advance prosecution, and without acquiescence to the rejection, claim 80 has been amended to exclude AIDS (in addition to rheumatoid arthritis and diabetes) as an autoimmune disease to be treated in the claimed method; claim 80 has also been amended to recite that the methods use a composition consisting essentially of one or more anti-IFN-α antibodies or antigen-binding fragments thereof.

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Therefore, because all of the limitations of claim 80 are not taught in Skurkovich et al., this claim and dependent claims 81-92 and 94-96 are not anticipated, and Applicants respectfully request that the rejection be withdrawn.

# C. Claim rejections—35 U.S.C. § 112—New matter

Claims 80-81 and 85-93 were rejected under 35 U.S.C. § 112 based upon the recitation "wherein the antibodies are not anti-IFN type I receptor antibodies". Because this recitation has been deleted from the claims, this rejection is now moot, and Applicants respectfully request that the rejection be withdrawn.

#### Conclusion

For the foregoing reasons, claims 80-92 and 94-96 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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Date of Signing:

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